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***IN THE UNITED STATES PATENT AND TRADEMARK OFFICE***

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| *Customer No.:* | 23643 |
| *Art Unit:* | 2616 |
| *Confirmation No.:* | 8938 |
| *Application No.:* | 09/555,718 |
| *Invention:* | INSTRUMENT SETUP UTILITY PROGRAM |
| *Inventor:* | Carol J. Batman, et al. |
| *Filed:* | January 12, 2001 |
| *Attorney Docket:* | 5727-65998 |
| *Examiner:* | Vu, Thong H. |

FILED MARCH 25, 2008

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This appeal brief is submitted in furtherance of the notice of appeal filed February 29, 2008. The Commissioner is hereby authorized to charge the $510.00 fee for this appeal brief, as well as any additional fees which may be required to constitute this a timely filed appeal brief, to Deposit Account No. 10-0435, with reference to Appellants' undersigned counsel's file 5727-65998.

REAL PARTY IN INTEREST

Roche Diagnostics Operations, Inc., is the real party in interest by virtue of an

assignment from the inventors to Boehringer Mannheim Corporation recorded in the records of the U. S. Patent and Trademark Office beginning at reel 9809, beginning at frame 0190, the merger of Boehringer Mannheim Corporation into Roche Diagnostics Corporation recorded in the records of the U. S. Patent and Trademark Office at reel 011954, beginning at frame 0957, and an assignment from Roche Diagnostics Corporation to Roche Diagnostics Operations, Inc., recorded in the records of the U. S. Patent and Trademark Office at reel 015215, beginning at frame 0061.

## RELATED APPEALS AND INTERFERENCES

There are no related proceedings to this appeal.

## STATUS OF CLAIMS

Claims 1-32, all of the claims in this application, are finally rejected. The rejections of all of claims 1-32 are on appeal

## STATUS OF AMENDMENTS

No amendments have been filed subsequent to the rejection from which this appeal is taken.

## SUMMARY OF CLAIMED SUBJECT MATTER

The invention may best be understood by referring to the following copies of appealed claims 1-32, annotated with parenthetic reference numbers and related notes from the detailed description. To facilitate reading of this summary, the claim language is in **bold** type.

1. **A method of configuring a hand-held instrument** (10, 10'; page 1, lines 7-18: "This is a related application to U.S.S.N. 60/067,512, titled INSTRUMENT, filed December 4, 1997, U.S.S.N. 60/067,499, filed December 4, 1997, titled INSTRUMENT SETUP UTILITY PROGRAM * * * and U. S. S. N. [ 09/555,659, now U. S. Patent 6,635,167], * * * filed on the same date as this application. * * * The disclosures of those applications are incorporated herein by reference. * * * This invention relates to a utility program useful in, for example, the setup of, and communication with, instruments of the general type described in U. S. S. N. 60/067,512") **having on-board circuitry for determining the concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **or a**

**control** (page 2, line 27) **and producing an electrical signal** (at terminals 96-1--96-4 of U. S. Patent 6,635,167) **representative thereof, the method comprising providing a configuring computer** (14) **having a first port** (18) **for transmitting to the hand-held instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **at least one of instructions for configuring** (page 4, line 5, *et seq.*) **the hand-held instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **and data for configuring** (page 4, line 5, *et seq.*) **the hand-held instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27), **providing on the instrument** (10, 10'; page 1, lines 7-18) **a second port** (17) **for receiving from the configuring computer** (14) **said at least one of instructions for configuring** (page 4, line 5, *et seq.*) **the hand-held instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **and data for configuring** (page 4, line 5, *et seq.*) **the hand-held instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27)**, connecting** (*via* serial cable 16) **said first port** (18) **directly to said second port** (17)**, transmitting said one of instructions for configuring** (page 4, line 5, *et seq.*) **the hand-held instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **and data for configuring** (page 4, line 5, *et seq.*) **said instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **from said first port** (18) **directly** (*via* serial cable 16) **to said second port** (17)**, receiving said one of instructions for configuring** (page 4, line 5, *et seq.*) **the hand-held instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **and data for configuring**

(page 4, line 5, *et seq.*) **said instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **directly** (*via* serial cable 16) **from said first port** (18) **at said second port** (17)**, and configuring** (page 4, line 5, *et seq.*) **said instrument** (10, 10'; page 1, lines 7-18) **according to said one of instructions for configuring** (page 4, line 5, *et seq.*) **the hand-held instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **and data for configuring** (page 4, line 5, *et seq.*) **said instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **transmitted from said first port** (18) **and received at said second port** (17).

2. **The method of claim 1 wherein providing a configuring computer** (14) **having a first port** (18) **for transmitting at least one of instructions for configuring** (page 4, line 5, *et seq.*) **the hand-held instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **and data for configuring** (page 4, line 5, *et seq.*) **the instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **comprises providing a configuring computer** (14) **having a first port** (18) **for transmitting instructions for configuring** (page 4, line 5, *et seq.*) **the hand-held instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27)**, and configuring** (page 4, line 5, *et seq.*) **the instrument** (10, 10'; page 1, lines 7-18) **in accordance with said instructions**.

3. **The method of claim 2 wherein providing a configuring computer** (14) **having a first port** (18) **for transmitting at least one of instructions for configuring** (page 4, line 5, *et seq.*) **the hand-held instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **and data for configuring** (page 4, line 5, *et seq.*) **the instrument** (10, 10'; page 1,

lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **comprises providing a configuring computer** (14) **having a first port** (18) **for transmitting data for configuring** (page 4, line 5, *et seq.*) **the instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27)**, and configuring** (page 4, line 5, *et seq.*) **the instrument** (10, 10'; page 1, lines 7-18) **in accordance with said data**.

4. **The method of claim 1 wherein providing a configuring computer** (14) **having a first port** (18) **for transmitting at least one of instructions for configuring** (page 4, line 5, *et seq.*) **the hand-held instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **and data for configuring** (page 4, line 5, *et seq.*) **the instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **comprises providing a configuring computer** (14) **having a first port** (18) **for transmitting data for configuring** (page 4, line 5, *et seq.*) **the instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27)**, and configuring** (page 4, line 5, *et seq.*) **the instrument** (10, 10'; page 1, lines 7-18) **in accordance with said data**.

5. **The method of claim 1 wherein the hand-held instrument** (10, 10'; page 1, lines 7-18) **further comprises a display** (42 of U. S. Patent 6,635,167) **for displaying information related to the determined concentration, transmitting said one of instructions for configuring** (page 4, line 5, *et seq.*) **the hand-held instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) or control (page 2, line 27) **and data for configuring** (page 4, line 5, *et seq.*) **said instrument** (10, 10'; page 1, lines 7-18) **for configuring** (page 4, line 5, *et seq.*) **the hand-held instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **from said first port** (18) **comprising transmitting said one of instructions for configuring** (page 4, line 5, *et seq.*)

**the hand-held instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **and data for configuring** (page 4, line 5, *et seq.*) **the hand-held instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **from said first port** (18) **to configure** (page 4, line 5, *et seq.*) **said display** (42 of U. S. Patent 6,635,167).

6. **The method of claim 2 wherein the hand-held instrument** (10, 10'; page 1, lines 7-18) **further comprises a display** (42 of U. S. Patent 6,635,167) **for displaying information related to the determined concentration, transmitting instructions for configuring** (page 4, line 5, *et seq.*) **the hand-held instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **from said first port** (18) **to configure** (page 4, line 5, *et seq.*) **said instrument** (10, 10'; page 1, lines 7-18) **comprising transmitting instructions for configuring** (page 4, line 5, *et seq.*) **the hand-held instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **for configuring** (page 4, line 5, *et seq.*) **said display** (42 of U. S. Patent 6,635,167).

7. **The method of claim 3 wherein the hand-held instrument** (10, 10'; page 1, lines 7-18) **further comprises a display** (42 of U. S. Patent 6,635,167) **for displaying information related to the determined concentration, transmitting said one of instructions for configuring** (page 4, line 5, *et seq.*) **the hand-held instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **and data for configuring** (page 4, line 5, *et seq.*) **said instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **from said first port** (18) **comprising transmitting data for configuring** (page 4, line 5, *et seq.*) **said instrument** (10, 10'; page 1, lines 7-18) **display** (42 of U. S. Patent 6,635,167).

8. **The method of claim 1 further comprising transmitting** (page 7,

line 15--page 8, line 4; page 9, line 15--page 11, line 29) **one of instructions concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **and data concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **from the second port** (17) **to the first port** (18).

9. **The method of claim 8 wherein transmitting** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **one of instructions concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **and data concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **from the second port** (17) **to the first port** (18) **comprises transmitting** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **data concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **from the instrument** (10, 10'; page 1, lines 7-18) **to the computer** (14).

10. **The method of claim 9 and further comprising updating** (page 9, lines 20-25) **a file in the computer** (14) **with the transmitted data** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27).

11. **The method of claim 2 further comprising transmitting** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **one of instructions concerning determined concentration of a medically significant component** (glucose, page 2, line 26) of a body fluid (blood or a blood fraction, page 2, lines 26-27) **and data concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **from the second port** (17) **to the first port** (18).

12. **The method of claim 11 wherein transmitting** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **one of instructions concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **and data concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **from the second port** (17) **to the first**

**port** (18) **comprises transmitting** (page 11, lines 1-12) **data concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **from the instrument** (10, 10'; page 1, lines 7-18) **to the computer** (14).

13. **The method of claim 12 and further comprising updating** (page 9, lines 15-25) **a file in the computer** (14) **with the transmitted data** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27).

14. **The method of claim 3 further comprising transmitting** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **one of instructions concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **and data concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **from the second port** (17) **to the first port** (18).

15. **The method of claim 14 wherein transmitting** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **one of instructions concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **and data concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **from the second port** (17) **to the first port** (18) **comprises transmitting** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **data concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **from the instrument** (10, 10'; page 1, lines 7-18) **to the computer** (14).

16. **The method of claim 15 and further comprising updating** (page 9, lines 20-25) **a file in the computer** (14) **with the transmitted data** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27).

17. **The method of claim 4 further comprising transmitting** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **one of instructions concerning determined concentration of a medically significant component** (glucose, page 2, line 26)

**of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **and data concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **from the second port** (17) **to the first port** (18).

18. **The method of claim 17 wherein transmitting** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **one of instructions concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **and data concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **from the second port** (17) **to the first port** (18) **comprises transmitting** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **data concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **from the instrument** (10, 10'; page 1, lines 7-18) **to the computer** (14).

19. **The method of claim 18 and further comprising updating** (page 9, lines 20-25) **a file in the computer** (14) **with the transmitted data** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27).

20. **The method of claim 5 further comprising transmitting** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **one of instructions concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **and data concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **from the second port** (17) **to the first port** (18).

21. **The method of claim 20 wherein transmitting** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **one of instructions concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **and data concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **from the second port** (17) **to the first port** (18) **comprises transmitting** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **data concerning determined concentration of a medically significant component**

(glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **from the instrument** (10, 10'; page 1, lines 7-18) **to the computer** (14).

22. **The method of claim 21 and further comprising updating** (page 9, lines 20-25) **a file in the computer** (14) **with the transmitted data** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27).

23. **The method of claim 6 further comprising transmitting** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **one of instructions concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **and data concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **from the second port** (17) **to the first port** (18).

24. **The method of claim 23 wherein transmitting** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **one of instructions concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **and data concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **from the second port** (17) **to the first port** (18) **comprises transmitting** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **data concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **from the instrument** (10, 10'; page 1, lines 7-18) **to the computer** (14).

25. **The method of claim 24 and further comprising updating** (page 9, lines 20-25) **a file in the computer** (14) **with the transmitted data** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27).

26. **The method of claim 7 further comprising transmitting** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **one of instructions concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **and data concerning determined concentration of a medically significant component** (glucose, page 2, line 26)

**of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **from the second port** (17) **to the first port** (18).

27. **The method of claim 26 wherein transmitting** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **one of instructions concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **and data concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **from the second port** (17) **to the first port** (18) **comprises transmitting** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **data concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **from the instrument** (10, 10'; page 1, lines 7-18) **to the computer** (14).

28. **The method of claim 27 and further comprising updating** (page 9, lines 20-25) **a file in the computer** (14) **with the transmitted data** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27).

29. **The method of claim 1, 2, 3, 4, 5, 6 or 7 wherein transmitting** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **said one of instructions for configuring** (page 4, line 5, *et seq.*) **the hand-held instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **and data for configuring** (page 4, line 5, *et seq.*) **said instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **from said first port** (18) **and receiving** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **said one of instructions for configuring** (page 4, line 5, *et seq.*) **the hand-held instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **and data for configuring** (page 4, line 5, *et seq.*) **said instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **at said second port** (17) **comprise transmitting** (page 7, line 15--page 8, line 4;

page 9, line 15--page 11, line 29) **said one of instructions for configuring** (page 4, line 5, *et seq.*) **the hand-held instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **and data for configuring** (page 4, line 5, *et seq.*) **said instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **through a fiber optic coupler** (16, page 3, lines 22-24) **from said first port** (18) **to said second port** (17).

30. **The method of claim 29 wherein the instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **comprises an instrument** (10, 10'; page 1, lines 7-18) **for determining the glucose concentration of blood, a blood fraction or a control** (page 2, line 27).

31. **The method of claim 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27 or 28 wherein transmitting** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **said one of instructions concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **and data concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **from the second port** (17) **to the first port** (18) **comprises transmitting** (page 7, line 15--page 8, line 4; page 9, line 15--page 11, line 29) **said one of instructions concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **and data concerning determined concentration of a medically significant component** (glucose, page 2, line 26) **of a body fluid** (blood or a blood fraction, page 2, lines 26-27) **via a modem** (20, 22) **from the second port** (17) **to the first port** (18).

32. **The method of claim 31 wherein the instrument** (10, 10'; page 1, lines 7-18) **for determining the concentration of the medically significant component** (glucose, page 2, line 26) **of the body fluid** (blood or a blood fraction, page 2, lines 26-27) **or control** (page 2, line 27) **comprises an instrument** (10, 10'; page 1, lines 7-18) **for determining the glucose concentration of blood, a blood fraction or a control** (page 2, line 27).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection to be reviewed on appeal are:

(1) whether claims 29 and 31 are objectionable under 37 C. F. R. § 1.75; and,

(2) whether claims 1-32 are 35 U. S. C. § 102 anticipated by Goodman U. S. Patent 5,827,180 (hereinafter Goodman). The Examiner referred in the final action to U. S. Patent 5307263, but that is a patent to Brown, not Goodman. The Examiner did the same thing in an earlier official action. Appellants' undersigned counsel telephoned the Examiner about this inconsistency. In a return telephone call, the Examiner confirmed that Goodman was the reference upon which the rejection was based. Appellants have assumed the Examiner had repeated that error in the current final action.

ARGUMENT

CLAIMS 29 AND 31 ARE NOT OBJECTIONABLE UNDER 37 C. F. R. § 1.75

As nearly as Appellants can determine, the Examiner rejected claims 29 and 31 because they are multiply dependent, citing MPEP § 608.01(n). MPEP § 608.01(n) provides in pertinent part:

> "608.01(n) Dependent Claims [R-5]
>
> I. MULTIPLE DEPENDENT CLAIMS
>
> 37 CFR 1.75 Claim(s).
>
> *****
>
> (c) One or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application. Any dependent claim which refers to more than one other claim ('multiple dependent claim') shall refer to such other claims in the alternative only."

Claim 29 begins "The method of claim 1, 2, 3, 4, 5, 6 or 7 wherein * * * ." Claims 1, 2, 3, 4, 5, 6 and 7 are independent or singly dependent. Claim 31 begins "The method of claim 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27 or 28 wherein * * * ." Claims 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27 and 28 are all singly dependent. Thus, MPEP § 608.01(n) specifically acknowledges that multiple dependent claims in the form of claims 29 and 31 are in proper form. This

rejection is therefore in error and should be reversed.

35 U. S. C. § 102 ANTICIPATION

In accordance with longstanding precedent construing 35 U. S. C. § 102, anticipation of a claim requires a showing that a single prior art reference discloses each and every element and limitation of the claim. See, e.g., *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 20, 57 U.S.P.Q. 2d 1057 (Fed. Cir. 2000); *Electro Medical Systems, S.A. v. Cooper Life Sciences, Inc.*, 34 F.3d 1048, 1052, 32 U.S.P.Q.2d 1017 (Fed. Cir. 1994); *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001 (Fed. Cir. 1991); *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1457, 221 USPQ 481, 485 (Fed. Cir. 1984); *In re King*, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986); *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1571 (Fed. Cir. 1986) ("The corollary of that rule is that absence from the reference of any claimed element negates anticipation."). The Federal Circuit Court of Appeals strictly construes the requirement for a showing of anticipation under 35 U. S. C. § 102:

> "[A]n invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim. The identical invention must be shown in as complete detail as is contained in the patent claim."

*Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) (citations omitted).

Furthermore, anticipation exists only if all the elements of the claimed invention are present in a product or process disclosed, expressly or inherently, in a single prior art reference. *Hazeltine Corp. v. RCA Corp.*, 468 U.S. 1228 (1984). Thus, a reference does not anticipate a claim if the claim contains any limitation that is neither literally nor inherently present in that reference.

THE EXAMINER'S POSITION

The Examiner takes the position that Goodman discloses

> "A method of configuring a hand-held instrument having on-board circuitry for determining the concentration of a medically significant component of a body fluid or a control and producing an electrical signal representative thereof, the method comprising providing a configuring computer having a

first port for transmitting to the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control at least one of instructions for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control and data for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control [Goodman, receives instruction from the host, col 6 lines 1; PDA and data transfer, an appropriate configured message device, col 6 line 65-col 7 line 20; data from medical device such as blood pressure, blood glucose, col 7 lines 35-45] providing on the instrument a second port for receiving from the configuring computer said at least one of instructions for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control and data for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control from the configuring computer, connecting said first port directly to said second port [Goodman, the customized patient management program, reprogrammed, modify, col 10 liens 37-60], transmitting said one of instructions for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control and data for configuring said instrument for determining the concentration of the medically significant component of the body fluid or control from said first port directly to said second port, receiving said one of instructions for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control and data for configuring said instrument for determining the concentration of the medically significant component of the body fluid or control directly from said first port at said second port [Goodman, two-way message capability, col 45 lines 30-40], and configuring said instrument according to said one of instructions for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control and data for configuring said instrument for determining the concentration of the medically significant component of the body fluid or control transmitted from said first port and received at said second port [Goodman, reprogram, col 6 lines 15-42]" (sic -- emphasis the Examiner's).

With respect to claims 2-32, the Examiner's expressed rationale is that "[c]laims 2-32 contain the identical limitations set froth in claim 1. Therefore claims 2-32 are rejected for the same rationale set forth in claim 1" (sic).

THE REFERENCE

Goodman teaches a method and system for a health network. In only one of the at least thirteen embodiments discussed by Goodman is the present claims' "hand-held instrument * * * for determining the concentration of a medically significant component of a body fluid or a control and producing an electrical signal representative thereof" disclosed. That is the embodiment of Goodman's Fig. 5 in which

> "[T]he data processor 10 is adapted to accept information input 71 from a medical device 70 that is network compatible. Tracking patient response to medical treatments outside of a health care setting (hospital, hospital, doctor office, clinic) require patients to monitor their blood pressure, blood sugar, pulse rate and other important physiological parameters. A clinician will rarely receive such data, and, even when it is received, it is subject to errors in reporting by the patient. Further, because the data is usually handwritten and previously recorded, it may be difficult to interpret and/or reconstruct accurately.
>
> "Accordingly, through the use of a custom interface to translate a signal of the medical device 70 corresponding to the measured parameter into a signal form acceptable to processor 10, the data obtained from basic medical devices 70, such as blood pressure, pulse, blood glucose meters, pulmonary function, cholesterol, etc., can be stored whenever the data is obtained, and then uploaded to the host computer 30 through the data processor 10 and/or message device 20. The design of such interfaces and the incorporation of such interfaces into devices 70 are straightforward and within the capabilities of those skilled in the art.
>
> "The host computer 30 receives data from the various information sources previously discussed, such as the message device 20, PHN compatible medical devices 70, the primary provider 4, and other health care facilities 5 (e.g., lab, pharmacy, hospital, or a secondary care provider (e.g., a medical specialist such as a surgeon, etc.)) . Using appropriate software, the host computer 30 analyzes data received from the various sources noted above, generates a report and forwards it to the primary provider 4, or to some other location 5 as appropriate. In this way, the primary provider 4 can receive periodic reports indicative of the patient's well-being and access the efficacy of the prescribed therapy without consuming the provider's office visit time or the patient's time for a personal visit.
>
> "Though appropriate software, the host computer 30 provides a variety of other network-related functions including

communications, network management, database manager, error/reliability manager and message/mail manager. The host computer 30 is preferably a main frame computer, although other hardware platforms are acceptable.

"In place of the host computer 30, one or more employees/representatives of the third party 3 may collect information, generate and maintain a record of information pertaining to a patient's health and transmit information either directly or indirectly to the patient 2, health care provider 4, or other location via telephone, facsimile transmission, electronic mail, or other communication means.

* * *

"Data entry, e.g., the peak flow measurements called for in Example 1, may be entered manually by the patient or by using the compatible medical devices 70 previously described. Alternatively, the requirement to enter the peak flow can be omitted in the simpler, less expensive message devices, which instead display the suitable options for the patient to self-medicate. Although a less desirable operation is achieved by this latter technology, it will nonetheless work sufficiently well to be useful."

Goodman, col. 7, line 22-col. 8, line 5 and col. 10, line 61-col. 11, line 2.

Appealed claim 1 requires

"providing a configuring computer *having a first port for transmitting to the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control at least one of instructions for configuring the hand-held instrument* for determining the concentration of the medically significant component of the body fluid or control *and data for configuring the hand-held instrument* for determining the concentration of the medically significant component of the body fluid or control, *providing on the instrument a second port for receiving from the configuring computer said at least one of instructions* for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control *and data* for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control, *connecting said first port directly to said second port, transmitting said one of instructions for configuring the hand-held instrument* for determining the concentration of the medically significant component of the body fluid or control *and data* for configuring said instrument for determining the concentration of the medically significant component of the body fluid or control *from said first port directly to said second port, receiving said one of instructions* for configuring the hand-held

> instrument for determining the concentration of the medically significant component of the body fluid or control *and data for configuring said instrument* for determining the concentration of the medically significant component of the body fluid or control *directly from said first port at said second port, and configuring said instrument according to said one of instructions* for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control *and data* for configuring said instrument for determining the concentration of the medically significant component of the body fluid or control *transmitted from said first port and received at said second port*." Emphasis Appellants'.

As the above-quoted passages from Goodman (the only passages in Goodman that even contemplate claim 1's specifically recited "hand-held instrument for determining the concentration of [a] medically significant component of [a] body fluid") make clear, Goodman neither discloses nor suggests claim 1's specifically recited

> "configuring computer having a first port for transmitting to the hand-held instrument * * * at least one of instructions for configuring the hand-held instrument * * * and data for configuring the hand-held instrument[,] * * * providing on the instrument a second port for receiving from the configuring computer said at least one of instructions * * * and data[,] * * * connecting said first port directly to said second port, transmitting said one of instructions * * * and data * * * from said first port directly to said second port, receiving said one of instructions * * * and data for configuring said instrument * * * directly from said first port at said second port, and configuring said instrument according to said one of instructions * * * and data * * * transmitted from said first port and received at said second port."

Paraphrasing the above-quoted passage from Goodman, a data processor 10 is adapted to accept information input 71 from a medical device 70 that is network compatible. A custom interface translates a signal of the medical device 70 corresponding to the measured parameter into a signal form acceptable to processor 10. Data such as blood glucose obtained from device 70 can be stored as the data is obtained, and then uploaded to the host computer 30 through the data processor 10 and/or message device 20. The host computer 30 receives data from the message device 20 (as well as from other personal health network 1-compatible devices 70, from the primary provider 4 and from other health care facilities 5). Using appropriate software, the host computer 30 analyzes data received from message device 20, any other personal health network 1-compatible devices 70, from the primary provider 4 and from other health care facilities 5), generates a report and forwards it to the primary provider

4, or health care facility 5 as appropriate. In this way, the primary provider 4 can receive periodic reports indicative of the patient's well-being and access the efficacy of the prescribed therapy without consuming the provider's office visit time or the patient's time for a personal visit. The host computer 30 preferably is a main frame computer, although other hardware platforms are acceptable. When programmed with appropriate software, the host computer 30 can provide other network-related functions, such as communications, network management, database manager, error/reliability management and message/mail management. In place of the host computer 30, one or more employees/representatives of the third party 3 may collect information, generate and maintain a record of information pertaining to a patient's health and transmit information either directly or indirectly to the patient 2, health care provider 4, or other location via telephone, facsimile transmission, electronic mail, or other communication means.

It is readily apparent from this description that the instrument 70 is not directly connected to any computer which is transmitting instructions or data through any such direct connection for configuring Goodman's instrument 70. This is required by claim 1. It is neither disclosed nor suggested by Goodman. Therefore, Goodman does not anticipate claim 1.

Claim 2 further limits claim 1 by claiming that the "configuring computer [transmits] instructions for configuring the hand-held instrument * * * and configur[es] the instrument in accordance with said instructions." Goodman neither discloses nor suggests any configuring computer for configuring Goodman's hand-held instrument 70 for determining the concentration of a medically significant component of a body fluid or control. Therefore, Goodman teaches neither transmitting configuring instructions nor configuring Goodman's instrument 70 based upon any such instructions. Therefore, Goodman does not anticipate claim 2.

Claim 6 further limits claim 2 to a "hand-held instrument [comprising] a display for displaying information related to the determined concentration, * * * [and] transmitting instructions * * * for configuring said display." Goodman neither discloses nor suggests any configuring computer for configuring any display contained in Goodman's hand-held instrument 70. Therefore, Goodman teaches neither transmitting instructions for configuring such a display nor configuring any such display contained in Goodman's instrument 70 based upon any such transmitted instructions. Therefore, Goodman does not anticipate claim 6.

Claims 23-25 depend directly or indirectly from claim 6 and are entitled to

allowance at least on this basis.

Claims 11-13 depend directly or indirectly from claim 2 and are entitled to allowance at least on this basis.

Claim 3 claims the configuring computer for transmitting both instructions and data for configuring the hand-held instrument. Goodman neither discloses nor suggests any configuring computer for configuring Goodman's hand-held instrument 70 for determining the concentration of a medically significant component of a body fluid or control. Therefore, Goodman teaches neither transmitting configuring instructions or data nor configuring Goodman's instrument 70 based upon any such instructions or data. Therefore, Goodman does not anticipate claim 3.

Claim 7 further limits claim 3 to a "hand-held instrument [comprising] a display for displaying information related to the determined concentration, * * * [and] transmitting data for configuring said instrument display." Goodman neither discloses nor suggests any configuring computer for configuring any display contained in Goodman's hand-held instrument 70. Therefore, Goodman teaches neither transmitting data for configuring such a display nor configuring any such display contained in Goodman's instrument 70 based upon any such transmitted data. Therefore, Goodman does not anticipate claim 7.

Claims 26-28 depend directly or indirectly from claim 7 and are entitled to allowance at least on this basis.

Claims 14-16 depend directly or indirectly from claim 3 and are entitled to allowance at least on this basis.

Claim 4 further limits claim 1 by claiming that the "configuring computer [transmits] data for configuring the hand-held instrument * * * and configur[es] the instrument in accordance with said data." Goodman neither discloses nor suggests any configuring computer for configuring Goodman's hand-held instrument 70 for determining the concentration of a medically significant component of a body fluid or control. Therefore, Goodman teaches neither transmitting configuring data nor configuring Goodman's instrument 70 based upon any such data. Therefore, Goodman does not anticipate claim 4.

Claims 17-19 depend directly or indirectly from claim 4 and are entitled to allowance at least on this basis.

Claim 5 further limits claim 1 to a "hand-held instrument [comprising] a display for displaying information related to the determined concentration, * * * [and] transmitting said one of instructions * * * and data * * * to configure said display."

Goodman neither discloses nor suggests any configuring computer for configuring any display contained in Goodman's hand-held instrument 70. Therefore, Goodman teaches neither transmitting instructions or data for configuring such a display nor configuring any such display contained in Goodman's instrument 70 based upon any such transmitted instructions or data. Therefore, Goodman does not anticipate claim 5.

Claims 20-22 depend directly or indirectly from claim 5 and are entitled to allowance at least on this basis.

Claims 8-10 depend directly or indirectly from claim 1 and are entitled to allowance at least on this basis.

Claim 29 further limits claim 1, 2, 3, 4, 5, 6 or 7 to "transmitting said one of instructions * * * and data for configuring [the hand-held] instrument for determining the concentration of the medically significant component of the body fluid or control through a fiber optic coupler from said first port to said second port." Goodman neither discloses nor suggests any configuring computer for configuring Goodman's hand-held instrument 70 for determining the concentration of a medically significant component of a body fluid or control. Therefore, Goodman teaches neither transmitting configuring instructions or data nor configuring Goodman's instrument 70 based upon any such instructions or data. Therefore, Goodman teaches neither transmitting configuring instructions nor configuring data to Goodman's instrument 70 through a fiber optic coupler from said first port to said second port. Therefore, Goodman does not anticipate claim 29.

Claim 30 depends from claim 29 and is entitled to allowance at least on this basis.

Claims 31 and 32 depend directly or indirectly from any one of claims 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27 and 28 and are entitled to allowance at least on this basis.

SUMMARY CONCLUSIONS

For the reasons noted above, the rejection of claims 29 and 31 under 37 C. F. R. § 1.75 is improper and should be reversed. For the reasons noted above, the rejection of claims 1-32 under 35 U. S. C. § 102 is improper and should be reversed. Such action is respectfully requested.

Resepctfully submitted,

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INDS02 RDC 961909

CLAIMS APPENDIX

The claims involved in this appeal follow:

1. A method of configuring a hand-held instrument having on-board circuitry for determining the concentration of a medically significant component of a body fluid or a control and producing an electrical signal representative thereof, the method comprising providing a configuring computer having a first port for transmitting to the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control at least one of instructions for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control and data for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control, providing on the instrument a second port for receiving from the configuring computer said at least one of instructions for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control and data for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control, connecting said first port directly to said second port, transmitting said one of instructions for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control and data for configuring said instrument for determining the concentration of the medically significant component of the body fluid or control from said first port directly to said second port, receiving said one of instructions for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control and data for configuring said instrument for determining the concentration of the medically significant component of the body fluid or control directly from said first port at said second port, and configuring said instrument according to said one of instructions for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control and data for configuring said instrument for determining the concentration of the medically significant component of the body fluid or control transmitted from said first port and received at said second port.

2. The method of claim 1 wherein providing a configuring computer having a first port for transmitting at least one of instructions for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control and data for configuring the instrument for determining the

concentration of the medically significant component of the body fluid or control comprises providing a configuring computer having a first port for transmitting instructions for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control, and configuring the instrument in accordance with said instructions.

3. The method of claim 2 wherein providing a configuring computer having a first port for transmitting at least one of instructions for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control and data for configuring the instrument for determining the concentration of the medically significant component of the body fluid or control comprises providing a configuring computer having a first port for transmitting data for configuring the instrument for determining the concentration of the medically significant component of the body fluid or control, and configuring the instrument in accordance with said data.

4. The method of claim 1 wherein providing a configuring computer having a first port for transmitting at least one of instructions for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control and data for configuring the instrument for determining the concentration of the medically significant component of the body fluid or control comprises providing a configuring computer having a first port for transmitting data for configuring the instrument for determining the concentration of the medically significant component of the body fluid or control, and configuring the instrument in accordance with said data.

5. The method of claim 1 wherein the hand-held instrument further comprises a display for displaying information related to the determined concentration, transmitting said one of instructions for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control and data for configuring said instrument for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control from said first port comprising transmitting said one of instructions for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control and data for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control from said first port to configure said display.

6. The method of claim 2 wherein the hand-held instrument further comprises a display for displaying information related to the determined concentration,

transmitting instructions for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control from said first port to configure said instrument comprising transmitting instructions for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control for configuring said display.

7. The method of claim 3 wherein the hand-held instrument further comprises a display for displaying information related to the determined concentration, transmitting said one of instructions for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control and data for configuring said instrument for determining the concentration of the medically significant component of the body fluid or control from said first port comprising transmitting data for configuring said instrument display.

8. The method of claim 1 further comprising transmitting one of instructions concerning determined concentration of a medically significant component of a body fluid and data concerning determined concentration of a medically significant component of a body fluid from the second port to the first port.

9. The method of claim 8 wherein transmitting one of instructions concerning determined concentration of a medically significant component of a body fluid and data concerning determined concentration of a medically significant component of a body fluid from the second port to the first port comprises transmitting data concerning determined concentration of a medically significant component of a body fluid from the instrument to the computer.

10. The method of claim 9 and further comprising updating a file in the computer with the transmitted data concerning determined concentration of a medically significant component of a body fluid.

11. The method of claim 2 further comprising transmitting one of instructions concerning determined concentration of a medically significant component of a body fluid and data concerning determined concentration of a medically significant component of a body fluid from the second port to the first port.

12. The method of claim 11 wherein transmitting one of instructions concerning determined concentration of a medically significant component of a body fluid and data concerning determined concentration of a medically significant component of a body fluid from the second port to the first port comprises transmitting data concerning determined concentration of a medically significant component of a body fluid from the

instrument to the computer.

13. The method of claim 12 and further comprising updating a file in the computer with the transmitted data concerning determined concentration of a medically significant component of a body fluid.

14. The method of claim 3 further comprising transmitting one of instructions concerning determined concentration of a medically significant component of a body fluid and data concerning determined concentration of a medically significant component of a body fluid from the second port to the first port.

15. The method of claim 14 wherein transmitting one of instructions concerning determined concentration of a medically significant component of a body fluid and data concerning determined concentration of a medically significant component of a body fluid from the second port to the first port comprises transmitting data concerning determined concentration of a medically significant component of a body fluid from the instrument to the computer.

16. The method of claim 15 and further comprising updating a file in the computer with the transmitted data concerning determined concentration of a medically significant component of a body fluid.

17. The method of claim 4 further comprising transmitting one of instructions concerning determined concentration of a medically significant component of a body fluid and data concerning determined concentration of a medically significant component of a body fluid from the second port to the first port.

18. The method of claim 17 wherein transmitting one of instructions concerning determined concentration of a medically significant component of a body fluid and data concerning determined concentration of a medically significant component of a body fluid from the second port to the first port comprises transmitting data concerning determined concentration of a medically significant component of a body fluid from the instrument to the computer.

19. The method of claim 18 and further comprising updating a file in the computer with the transmitted data concerning determined concentration of a medically significant component of a body fluid.

20. The method of claim 5 further comprising transmitting one of instructions concerning determined concentration of a medically significant component of a body fluid and data concerning determined concentration of a medically significant component of a body fluid from the second port to the first port.

21. The method of claim 20 wherein transmitting one of instructions concerning determined concentration of a medically significant component of a body fluid and data concerning determined concentration of a medically significant component of a body fluid from the second port to the first port comprises transmitting data concerning determined concentration of a medically significant component of a body fluid from the instrument to the computer.

22. The method of claim 21 and further comprising updating a file in the computer with the transmitted data concerning determined concentration of a medically significant component of a body fluid.

23. The method of claim 6 further comprising transmitting one of instructions concerning determined concentration of a medically significant component of a body fluid and data concerning determined concentration of a medically significant component of a body fluid from the second port to the first port.

24. The method of claim 23 wherein transmitting one of instructions concerning determined concentration of a medically significant component of a body fluid and data concerning determined concentration of a medically significant component of a body fluid from the second port to the first port comprises transmitting data concerning determined concentration of a medically significant component of a body fluid from the instrument to the computer.

25. The method of claim 24 and further comprising updating a file in the computer with the transmitted data concerning determined concentration of a medically significant component of a body fluid.

26. The method of claim 7 further comprising transmitting one of instructions concerning determined concentration of a medically significant component of a body fluid and data concerning determined concentration of a medically significant component of a body fluid from the second port to the first port.

27. The method of claim 26 wherein transmitting one of instructions concerning determined concentration of a medically significant component of a body fluid and data concerning determined concentration of a medically significant component of a body fluid from the second port to the first port comprises transmitting data concerning determined concentration of a medically significant component of a body fluid from the instrument to the computer.

28. The method of claim 27 and further comprising updating a file in the computer with the transmitted data concerning determined concentration of a medically

significant component of a body fluid.

29. The method of claim 1, 2, 3, 4, 5, 6 or 7 wherein transmitting said one of instructions for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control and data for configuring said instrument for determining the concentration of the medically significant component of the body fluid or control from said first port and receiving said one of instructions for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control and data for configuring said instrument for determining the concentration of the medically significant component of the body fluid or control at said second port comprise transmitting said one of instructions for configuring the hand-held instrument for determining the concentration of the medically significant component of the body fluid or control and data for configuring said instrument for determining the concentration of the medically significant component of the body fluid or control through a fiber optic coupler from said first port to said second port.

30. The method of claim 29 wherein the instrument for determining the concentration of the medically significant component of the body fluid or control comprises an instrument for determining the glucose concentration of blood, a blood fraction or a control.

31. The method of claim 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27 or 28 wherein transmitting said one of instructions concerning determined concentration of a medically significant component of a body fluid and data concerning determined concentration of a medically significant component of a body fluid from the second port to the first port comprises transmitting said one of instructions concerning determined concentration of a medically significant component of a body fluid and data concerning determined concentration of a medically significant component of a body fluid via a modem from the second port to the first port.

32. The method of claim 31 wherein the instrument for determining the concentration of the medically significant component of the body fluid or control comprises an instrument for determining the glucose concentration of blood, a blood fraction or a control.

## EVIDENCE APPENDIX

Nothing is included with this appendix.

## RELATED PROCEEDINGS APPENDIX

Nothing is included with this appendix.